FDA-Approved Alternative Requirement – Carestream

Correction Period When Components of the Carestream DirectView Full-Field Digital Mammography (FFDM) System Fail Quality Control Tests

On February 8, 2011, FDA approved an Alternative Standard regarding the time period allowed for corrective action to be taken for the Carestream DirectView CR with Mammography Feature FFDM imaging system, if certain quality control test results fall outside of specified action limits. The time period depends on the particular test which fails and also on whether the test pertains to the image acquisition system or the image display components. This division makes it clear that when the test failure is related to the acquisition of images only, image acquisition must cease until the problem is corrected but image interpretation can continue. Similarly if the test failure is related to the interpretation of images, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The Alternative Standard is described below. **[This alternative standard only applies to Annual Surveys and routine QC; it does not apply to Equipment Evaluations.]**

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

21 CFR 900.12(e)(8): *Use of test results*

> (ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:
>
> > (A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;
> >
> > (B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

The approved alternative is:

21 CFR 900.12(e)(8): *Use of test results*

> (ii) If the test results for the Carestream DirectView CR System with the Mammography Feature, fall outside the action limits, *the source of the problem shall be identified and corrective actions shall be taken*:
>
> > (A) If any of the following quality control tests that evaluate the performance of the image acquisition components of the Carestream DirectView CR system produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be

identified and corrective action shall be taken before any further examinations are performed using that component. If the component that caused the failure can be replaced by an alternative approved device, then clinical imaging may be continued:

(1) Erased Screen Test
(2) Phantom Test
(3) CNR weekly Check
(4) Compression
(5) Cassette/Phosphor Screen Artifact Test
(6) Spatial Frequency Response Test
(7) Geometric Accuracy Test
(8) Cassette Exposure Response Test
(9) Dose

(B) If any of the following quality control tests that evaluate the performance of a diagnostic device used for mammographic image interpretation (i.e. laser printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation. Image acquisition can be continued. An alternative approved diagnostic device shall be used for mammographic image interpretation:

(1) Phantom Test
(2) Printer Quality Control
(3) Diagnostic Monitor Quality Control
(4) Viewing Conditions

(C) If any of the following quality control tests that evaluate the performance of the X-ray unit/ room or exposure function or the diagnostic devices used for mammographic image interpretation produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation may be continued during this period:

(1) Mammographic Unit Visual Checklist
(2) Repeat Analysis
(3) Scanner Uniformity
(4) Scanner Response Linearity Test
(5) AEC System Performance/ Constancy Test
(6) Mammographic Unit Assembly Evaluation
(7) Mammographic Unit Collimation Assessment
(8) Beam Quality and Half-Value Layer
(9) kVp Accuracy and Reproducibility
(10) Breast Entrance Exposure and Radiation Output